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Predictors of Peri-Operative Risk Acceptance by Vascular Surgery Patients at a Tertiary Level Hospital (MMED)

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Discipline of Anaesthesiology and Critical Care

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PREDICTORS OF PERI-OPERATIVE RISK ACCEPTANCE BY VASCULAR SURGERY PATIENTS AT A TERTIARY LEVEL HOSPITAL (MMED)

INTRODUCTION

South African vascular surgical patients have an elevated cardiac risk following non-cardiac surgery and a high co-existent morbidity.[1, 2] The decision whether to proceed with surgery is multidimensional. Patients need to balance the considerations in favour of surgery with those favouring conservative treatment, which requires weighing peri-operative risk against morbidity associated with non-surgical treatment.

This study was conducted as part of my Masters in Medicine (MMED) in order to determine the potential predictors of peri-operative risk acceptance by South African vascular surgical patients at a tertiary level hospital in KwaZulu-Natal.

DEFINITIONS

Decision-making
A cognitive process in which available information is evaluated and integrated in order to reach a conclusion or a course of action among several alternative possibilities. [3]

Shared decision-making
This is a decision-making process involving collaboration between the patient and their physician to make medical decisions based on current evidence, and the patient's subjectivities. [4]

Peri-operative risk
This was defined as a risk of adverse outcomes associated with surgery during the hospital admission for surgery (e.g. death and major adverse cardiac events).

Visual analogue scale (VAS)
An instrument used to quantify subjective characteristics or attitudes that ranges across a continuum and cannot be measured directly. It is commonly represented as a horizontal line from 0mm to 100mm. The endpoints of the line represent the extremes of the parameter being measured.[5]

Impulsivity
A personality trait associated with willingness to take risks, lack of planning and future orientation, and making quick decisions.[6]

Barratt Impulsiveness Scale II (BIS II)
A self-reported instrument devised to assess the construct of impulsiveness.[7] It is composed of 30 items that are scored on a 4-point scale to yield a total score. The BIS II can be further divided into six first order factors (i.e. attention, motor, self-control, cognitive complexity, perseverance and cognitive instability impulsiveness) and three second order factors (i.e. attention, motor and non planning impulsiveness).[7] A total score of 72 represents a highly impulsive individual, a total

score of 52-71 represents the normal limits of impulsiveness and a total score of less than 52 represents a cautious individual.[7]

South African Vascular Surgical Cardiac Risk Index (SAVS-CRI)

A cardiovascular risk stratification index that can be used in South African patients undergoing vascular surgery to predict the risk of peri-operative major adverse cardiovascular events (MACEs).[8] It consists of the following six independent risk factors: patient's age, history of ischaemic heart disease, chronic β-blockade, a history of diabetes, a prior history of coronary revascularisation and the vascular surgical procedure.[8] A total score of <7 represents the low-risk group, a total score of 7-11 represents the intermediate-risk group and a total score of >11 represents the high-risk group.

BACKGROUND

There has been an increase in the number of patients undergoing non-cardiac surgery globally.[1,9] Vascular surgical patients have an elevated cardiac risk following non-cardiac surgery. Considerations in this group are varied from poor premorbid functioning, anatomical concerns, surgical complications, medical comorbidities and uncertainty of a suitable outcome. As a result, the decision-making process leading to surgical intervention is complex and creates a predicament for patients i.e. should they or should they not accept the peri-operative risk when consenting to vascular surgery in order to achieve a suitable outcome.[1, 2, 10, 11]

Decision-making is a cognitive function which reflects on the consequences of a certain choice[3] and requires deliberation on numerous alternatives and contemplation about future outcomes.[12] In the literature, 'decisions under ambiguity' and 'decisions under risk' are differentiated. Decisions under ambiguity represent situations where the results of the decision are not defined and there is no information regarding the probability of a positive or negative outcome whereas, decisions under risk are described as situations where the outcomes are stipulated and associated possibilities are identified or are quantifiable.[3, 13]

Recently, the concept of decision-making in medicine has progressed from solely the physician's recommendations on surgical intervention to the current concept of shared decision-making.[4]

Patient autonomy and their readiness to give informed consent for surgery are affected by a myriad of factors.[14] There are a multitude of studies, which have looked at decision-making processes in a variety of patient groups. For example, impaired decisions were shown in patients with orbitofrontal lesions,[3] drug addicts,[15-17] obesity,[18] obsessive compulsive disorder,[15] criminals,[19] fibromyalgia and temporomandibular disease.[20]

However, very few studies have related pain to a decision measure such as the study by Apkarian et al.[21, 22] They determined that chronic back pain and chronic regional pain syndrome patients performed worse on an emotional decision-making task that was assessed using the Iowa Gambling Task. [21] Furthermore, the poor performance of the chronic back pain patients was correlated to their pain intensity.[21] Another study suggested that the duration of pain and the intensity thereof were the most important factors for patients in their decision to proceed with lumbar spine fusion.[23, 24]

Based on clinical experience, it would appear that patients in severe pain are more inclined to accept risk than their counterparts in mild pain[24] but there still remains a paucity of published data to support this opinion and very few studies such as Bono et al[24] have shown that the severity of pain is the most important factor in a patient's decision to accept peri-operative risk when considering surgical intervention.

The aim of our study was to determine the proportional contributions of i) pain, ii) impulsivity, iii) patients' perception of the benefits of surgery, iv) patients' perception of peri-operative risk and v) predicted peri-operative risk on the acceptance of peri-operative risk by vascular surgical patients.

METHODS

Ethical approval for this study (Ethics Reference Number BE 391/13) was obtained from the Biomedical Research Ethics Committee and the Postgraduate Education Committee of the University of KwaZulu-Natal, South Africa on 20 February 2014.

Study setting
Inkosi Albert Luthuli Central Hospital, eThekwini District Complex, Durban, KwaZulu-Natal, South Africa.

Study design
Prospective, correlational study.

Population and Study Sample
Vascular surgical patients at Inkosi Albert Luthuli Central Hospital during April to June 2014.

Inclusion criteria:
All vascular surgical patients over 45 years of age who required surgery but in whom the decision to proceed with surgery had not yet been made.

Exclusion criteria:
Patients who declined to give informed consent to participate in the study.

Selection of Sample and Sample Size
We used random sampling from vascular surgical clinic patients. It had been determined that a minimum sample size of 55 would achieve 90% power to detect an R^2 of 0.20000 attributed to 3 independent variable(s) using an F-test with a significance level (α) of 0.01000. The variables tested were adjusted for an additional 3 independent variable(s) with an R^2 of 0.30000. Hence, we recruited 60 patients into our study.

Sources of Data
A structured standardised questionnaire was designed and administered to the vascular surgical patients in either English or isiZulu. A pilot study was conducted at the same site in March 2014. These patients were not included in the final study but their responses and queries were used to improve the structured standardised questionnaire.

Our questionnaire consisted of the following sections:

1. Demographic data (age, sex, race, highest level of education)
2. Pain Assessment which contained a pain VAS and an assessment of the efficacy of current analgesic management
3. Impulsivity screen using the Barratt Impulsiveness Scale II (BIS II)
4. Patients' perception of surgery i.e. the perceived benefits of surgery and perceived peri-operative risk by using an adapted VAS
5. Patients' predicted peri-operative risk according to the South African Vascular Surgical Cardiac Risk Index (SAVS-CRI)
6. Acceptance of predicted peri-operative risk using an adapted VAS

Measures to Ensure Validity

1. Internal
   A pilot study was conducted at the same site in March 2014 and served to validate the questionnaire and clarify any misconceptions.
2. Reduction of bias
   Selection bias - Random sampling was conducted from vascular surgical clinic patients in whom the decision to proceed with surgery had not yet been made
   Information bias - Questionnaires were anonymous.
3. External
   This study was conducted at one site only (Inkosi Albert Luthuli Central Hospital).

Collection of Data

A one on one structured standardised questionnaire was administered to the patients by the principal investigator.

Exposure Assessment

Acceptance of peri-operative risk using an adapted VAS.

Data Management

Data was collected on paper case record forms for every patient recruited. Data was input into Microsoft excel and kept anonymous. Access was username and password protected by the investigators.

Data Analysis Strategies

Categorical data were analysed using descriptive statistics and presented as proportions. Continuous data were analysed using descriptive statistics and presented as mean and standard deviation. The association between the potential determinants of the acceptance of surgical risk were analysed using Pearson's correlation coefficient, as all variables were normally distributed. Linear regression analysis was used to determine independent predictors of an acceptance of peri-operative risk. A p-value of < 0.05 was considered to be statistically significant. Results are presented as odds ratios (OR) and 95% confidence intervals (CI). All statistical analyses were performed using SPSS version 22.

RESULTS

Sixty patients were prospectively recruited into the study between April 2014 and June 2014. The characteristics of our study cohort are shown in Table 1.

Table 1 Baseline patient characteristics, expressed as mean (standard deviation) or number (proportion).

	Total (n = 60)
Age; years	64.15 (9.7)
Sex	
Male	37 (61.7%)
Female	23 (38.3%)
Highest level of education	
Tertiary	6 (10%)
High school or less	54 (90%)
Pain VAS score; mm	57.05 (33.02)
BIS II score	63.83 (6.97)
Surgical diagnosis	
Peripheral vascular disease	48 (80%)
Carotid artery disease	7 (11.7%)
Carotid artery disease and peripheral vascular disease	4 (6.7%)
Infra renal abdominal aortic aneurysm	1 (1.7%)
Patients' perception of the benefits of surgery VAS score; mm	74.95 (25.09)
Patients' perception of peri-operative risk VAS score; mm	40.13 (29.55)
SAVS-CRI score	6.7 (2.8)
SAVS-CRI risk group	
High	1 (1.7%)
Intermediate	32 (53.3%)
Low	27 (45%)
Actual subsequent patient management	
Conservative management	13 (21.7%)
Surgery	47 (78.3%)

** VAS: Visual analogue scale, † mm: millimetres, ‡ BIS II: Barratt Impulsiveness Scale II, § SAVS-CRI: South African Vascular Surgical Cardiac Risk Index*

The majority of the patients had a high school or lower level of education. Approximately 10% of the cohort had no pain (VAS 0mm) and their primary diagnosis was predominantly carotid artery disease. The remainder of the cohort reported moderate to severe pain (mean VAS 57.05mm, SD 33.02) and the primary diagnosis in 80% of our cohort was peripheral vascular disease. In addition, 6.7% of patients had maximal pain (VAS 100mm) and their primary diagnosis was peripheral vascular disease. Fifty patients (83%) had a Barratt Impulsiveness Scale II (BIS II) score of 52-71, which is by definition normal (mean BIS II score 63.83, SD 6.97).

The only significant correlation was between the predicted peri-operative risk (SAVS-CRI score) and the patients' perception of their peri-operative risk (r = 0.33 p = 0.01). The remaining correlations between the potential predictors of acceptance of peri-operative risk were not statistically significant.

The results of the linear regression are shown in Table 2.

Table 2 Linear regression analysis for acceptance of peri-operative risk by vascular surgical patients.

	β (95% CI)	p value
Pain VAS score	0.07 (-0.16–0.28)	0.582
BIS II score	0.12 (-0.59–1.59)	0.360
Patients' perception of the benefits of surgery VAS score	0.36 (0.14–0.70)	0.005
Patients' perception of peri-operative risk VAS score	-0.05 (-0.31–0.22)	0.711
Predicted peri-operative risk - SAVS-CRI score	-0.26 (-5.48–0.08)	0.057

** β: standardised coefficient, † VAS: Visual analogue scale, ‡ BIS II: Barratt Impulsiveness Scale II, § SAVS-CRI: South African Vascular Surgical Cardiac Risk Index*

The perceived benefit of surgery by the patient (β 0.36, 95% CI 0.14–0.70, p = 0.005) was the only predictor of peri-operative risk acceptance. We did not find any statistically significant association between pain (β 0.07, 95% CI -0.16–0.28, p = 0.582), impulsivity (β 0.12, 95% CI -0.59–1.59, p = 0.360), the patients' perception of peri-operative risk (β -0.05, 95% CI -0.31–0.22, p = 0.711) and predicted peri-operative risk (β -0.26, 95% CI -5.48–0.08, p = 0.057) on acceptance of peri-operative risk in this population.

DISCUSSION

Our study demonstrated that the only significant predictor of acceptance of peri-operative risk is the perceived benefits of surgery by the patient. There were no statistically significant associations between pain, impulsivity, patients' perception of peri-operative risk and predicted peri-operative risk on the outcome of acceptance of peri-operative risk in this cohort.

There is a noticeable void in the literature as limited studies have investigated the factors, which influence acceptance of peri-operative risk by surgical patients.[23-27] Our findings are relevant, as this is the first study to determine the proportional contribution of pain, impulsivity, patients' perception of the benefits of surgery, patients' perception of peri-operative risk and predicted peri-operative risk on acceptance of peri-operative risk by a surgical population.

The only predictor of acceptance of peri-operative risk was the patients' perception of the benefits of surgery. According to the Institute of Medicine, 'patient-centered care' is one of the key components of health quality.[28] Shared decision-making plays a pivotal role in this paradigm.[28-31] The fundamentals of shared decision-making rely on the doctor collaborating with the patient to share information regarding the risks, benefits and limits of available treatment options that are based on current research evidence.[28-32] In doing so, a consensus on medical treatment is reached that is congruent with the patient's values, goals and preferences.[28-32] This ideal model of patient decision presupposes that patients receive accurate information about risks, costs and benefits, that they accurately represent that information when deliberating, and that their reasoning does not systematically drive them away from conclusions that are in their genuine interests. There is reason to doubt that these assumptions are generally true.[33]

Some personality traits such as impulsivity have been associated with decision-making deficits (i.e. an impulsive person exhibits reduced reflection on the consequences of their choice and has a high sensitivity to delayed rewards or a stronger preference for relatively immediate rewards).[15, 34, 35] Most patients in our study were not pathologically impulsive and there was no significant relationship between impulsivity and acceptance of peri-operative risk in our study. As a result we could not explore these associations further.

Another implication of our main finding is that patient involvement in treatment decision-making must be emphasised and the patient needs to actively participate in shared decision making. Further work should focus on understanding the impact of the surgical consultation on patient perception of surgery and in particular ascertaining what factors might be positively or negatively influencing patients' perception of surgery.

In general, limited research has been published which relates a decision measure to pain. Apkarian et al[21, 22] concluded that chronic back pain and chronic regional pain syndrome patients are significantly impaired on an emotional decision-making task (the Iowa Gambling Task) and the performance of chronic back pain patients was correlated to their pain intensity. In another study, Bono et al[24] determined that the severity of pain is the most important factor in patient's decision to accept surgical complications when considering lumbar spine fusion and Andrade et al found that recent pain influenced decisions about the scheduling of future treatments.[36] Unlike previous studies, our study suggests that the relationship between pain and acceptance of peri-operative risk is negligible. However, most patients in our study were not in severe pain and reported satisfactory pain control with their current analgesic management. Further research is needed to explore the relationship between severe pain and acceptance of peri-operative risk

Of interest, the only significant correlation was between the predicted peri-operative risk (SAVS-CRI score) and the patient's perception of their peri-operative risk. This suggests that the patients understood the concept of surgery-associated risk. Consequently, the fact that patient decisions were strongly determined by perception of benefits, but weakly by perception of risks is suggestive, but does not point to a specific model of the patient decision process.

LIMITATIONS

Our study has several potential limitations:

- ✓ Most patients did not report severe pain and most participating patients did report satisfactory pain control with their current analgesic management.
- ✓ The majority of patients had impulsivity scores in the normal range.

It is possible that a study population with greater variation in both pain severity and impulsivity might enable the detection of an association.

- ✓ Our study population represents a predominantly relatively poorly educated patient population from a specific cultural group.

This may be an advantage as to date the majority of literature in the behavioural and cognitive sciences is based upon undergraduate students at highly developed western institutions

- ✓ We used an adapted VAS to assess the patients' perception of the benefits of surgery, perceived peri-operative risk and acceptance of peri-operative risk.

Whilst this may be criticised, we opted for an adapted VAS instead of other decision analysis instruments based on its simplicity and the low numeracy level of our study population.

- ✓ The subgroup of patients with carotid artery disease may have potentially confounded the relationship between pain and acceptance of peri-operative risk in this cohort.

A post hoc analysis was conducted where the patients with carotid artery disease were removed from the analysis and all study outcomes were unchanged. Again, the perceived benefit of surgery by the patient remained the only predictor of peri-operative risk acceptance (β 0.36, 95% CI 0.08–0.67, p = 0.013).

CONCLUSION

There are several factors that influence a patient's decision to proceed with surgery but the manner in which risks are balanced and information integrated still remains poorly understood. We have shown that the perceived benefit of surgery is an important predictor of acceptance of peri-operative risk. But, we have been unable to adequately address the importance of severe pain and an impulsive personality on acceptance of peri-operative risk. Further research is required to adequately address these issues.

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We used random sampling from vascular surgical clinic patients. It had been determined that a minimum sample size of 55 would achieve 90% power to detect an R^2 of 0.20000 attributed to 3 independent variable(s) using an F-test with a significance level (α) of 0.01000. The variables tested were adjusted for an additional 3 independent variable(s) with an R^2 of 0.30000. Hence, we recruited 60 patients into our study.

Sources of Data
A structured standardised questionnaire was designed and administered to the vascular surgical patients in either English or isiZulu. A pilot study was conducted at the same site in March 2014. These patients were not included in the final study but their responses and queries were used to improve the structured standardised questionnaire.

Our questionnaire consisted of the following sections:

1. Demographic data (age, sex, race, highest level of education)
2. Pain Assessment which contained a pain VAS and an assessment of the efficacy of current analgesic management
3. Impulsivity screen using the Barratt Impulsiveness Scale II (BIS II)
4. Patients' perception of surgery i.e. the perceived benefits of surgery and perceived peri-operative risk by using an adapted VAS
5. Patients' predicted peri-operative risk according to the South African Vascular Surgical Cardiac Risk Index (SAVS-CRI)
6. Acceptance of predicted peri-operative risk using an adapted VAS

Measures to Ensure Validity

1. Internal
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A one on one structured standardised questionnaire was administered to the patients by the principal investigator.

Exposure Assessment

Acceptance of peri-operative risk using an adapted VAS.

Data Management

Data was collected on paper case record forms for every patient recruited. Data was input into Microsoft excel and kept anonymous. Access was username and password protected by the investigators.

Data Analysis Strategies

Categorical data were analysed using descriptive statistics and presented as proportions. Continuous data were analysed using descriptive statistics and presented as mean and standard deviation. The association between the potential determinants of the acceptance of surgical risk were analysed using Pearson's correlation coefficient, as all variables were normally distributed. Linear regression analysis was used to determine independent predictors of an acceptance of peri-operative risk. A p-value of < 0.05 was considered to be statistically significant. Results are presented as odds ratios (OR) and 95% confidence intervals (CI). All statistical analyses were performed using SPSS version 22.

RESULTS

Sixty patients were prospectively recruited into the study between April 2014 and June 2014. The characteristics of our study cohort are shown in Table 1.

Table 1 Baseline patient characteristics, expressed as mean (standard deviation) or number (proportion).

	Total (n = 60)
Age; years	64.15 (9.7)
Sex	
Male	37 (61.7%)
Female	23 (38.3%)
Highest level of education	
Tertiary	6 (10%)
High school or less	54 (90%)
Pain VAS score; mm	57.05 (33.02)
BIS II score	63.83 (6.97)
Surgical diagnosis	
Peripheral vascular disease	48 (80%)
Carotid artery disease	7 (11.7%)
Carotid artery disease and peripheral vascular disease	4 (6.7%)
Infra renal abdominal aortic aneurysm	1 (1.7%)
Patients' perception of the benefits of surgery VAS score; mm	74.95 (25.09)
Patients' perception of peri-operative risk VAS score; mm	40.13 (29.55)
SAVS-CRI score	6.7 (2.8)
SAVS-CRI risk group	
High	1 (1.7%)
Intermediate	32 (53.3%)
Low	27 (45%)
Actual subsequent patient management	
Conservative management	13 (21.7%)
Surgery	47 (78.3%)

** VAS: Visual analogue scale, † mm: millimetres, ‡ BIS II: Barratt Impulsiveness Scale II, § SAVS-CRI: South African Vascular Surgical Cardiac Risk Index*

The majority of the patients had a high school or lower level of education. Approximately 10% of the cohort had no pain (VAS 0mm) and their primary diagnosis was predominantly carotid artery disease. The remainder of the cohort reported moderate to severe pain (mean VAS 57.05mm, SD 33.02) and the primary diagnosis in 80% of our cohort was peripheral vascular disease. In addition, 6.7% of patients had maximal pain (VAS 100mm) and their primary diagnosis was peripheral vascular disease. Fifty patients (83%) had a Barratt Impulsiveness Scale II (BIS II) score of 52-71, which is by definition normal (mean BIS II score 63.83, SD 6.97).

The only significant correlation was between the predicted peri-operative risk (SAVS-CRI score) and the patients' perception of their peri-operative risk (r = 0.33 p = 0.01). The remaining correlations between the potential predictors of acceptance of peri-operative risk were not statistically significant.

The results of the linear regression are shown in Table 2.

Table 2 Linear regression analysis for acceptance of peri-operative risk by vascular surgical patients.

	β (95% CI)	p value
Pain VAS score	0.07 (-0.16–0.28)	0.582
BIS II score	0.12 (-0.59–1.59)	0.360
Patients' perception of the benefits of surgery VAS score	0.36 (0.14–0.70)	0.005
Patients' perception of peri-operative risk VAS score	-0.05 (-0.31–0.22)	0.711
Predicted peri-operative risk - SAVS-CRI score	-0.26 (-5.48–0.08)	0.057

** β: standardised coefficient, † VAS: Visual analogue scale, ‡ BIS II: Barratt Impulsiveness Scale II, § SAVS-CRI: South African Vascular Surgical Cardiac Risk Index*

The perceived benefit of surgery by the patient (β 0.36, 95% CI 0.14–0.70, p = 0.005) was the only predictor of peri-operative risk acceptance. We did not find any statistically significant association between pain (β 0.07, 95% CI -0.16–0.28, p = 0.582), impulsivity (β 0.12, 95% CI -0.59–1.59, p = 0.360), the patients' perception of peri-operative risk (β -0.05, 95% CI -0.31–0.22, p = 0.711) and predicted peri-operative risk (β -0.26, 95% CI -5.48–0.08, p = 0.057) on acceptance of peri-operative risk in this population.

DISCUSSION

Our study demonstrated that the only significant predictor of acceptance of peri-operative risk is the perceived benefits of surgery by the patient. There were no statistically significant associations between pain, impulsivity, patients' perception of peri-operative risk and predicted peri-operative risk on the outcome of acceptance of peri-operative risk in this cohort.

There is a noticeable void in the literature as limited studies have investigated the factors, which influence acceptance of peri-operative risk by surgical patients.[23-27] Our findings are relevant, as this is the first study to determine the proportional contribution of pain, impulsivity, patients' perception of the benefits of surgery, patients' perception of peri-operative risk and predicted peri-operative risk on acceptance of peri-operative risk by a surgical population.

The only predictor of acceptance of peri-operative risk was the patients' perception of the benefits of surgery. According to the Institute of Medicine, 'patient-centered care' is one of the key components of health quality.[28] Shared decision-making plays a pivotal role in this paradigm.[28-31] The fundamentals of shared decision-making rely on the doctor collaborating with the patient to share information regarding the risks, benefits and limits of available treatment options that are based on current research evidence.[28-32] In doing so, a consensus on medical treatment is reached that is congruent with the patient's values, goals and preferences.[28-32] This ideal model of patient decision presupposes that patients receive accurate information about risks, costs and benefits, that they accurately represent that information when deliberating, and that their reasoning does not systematically drive them away from conclusions that are in their genuine interests. There is reason to doubt that these assumptions are generally true.[33]

Some personality traits such as impulsivity have been associated with decision-making deficits (i.e. an impulsive person exhibits reduced reflection on the consequences of their choice and has a high sensitivity to delayed rewards or a stronger preference for relatively immediate rewards).[15, 34, 35] Most patients in our study were not pathologically impulsive and there was no significant relationship between impulsivity and acceptance of peri-operative risk in our study. As a result we could not explore these associations further.

Another implication of our main finding is that patient involvement in treatment decision-making must be emphasised and the patient needs to actively participate in shared decision making. Further work should focus on understanding the impact of the surgical consultation on patient perception of surgery and in particular ascertaining what factors might be positively or negatively influencing patients' perception of surgery.

In general, limited research has been published which relates a decision measure to pain. Apkarian et al[21, 22] concluded that chronic back pain and chronic regional pain syndrome patients are significantly impaired on an emotional decision-making task (the Iowa Gambling Task) and the performance of chronic back pain patients was correlated to their pain intensity. In another study, Bono et al[24] determined that the severity of pain is the most important factor in patient's decision to accept surgical complications when considering lumbar spine fusion and Andrade et al found that recent pain influenced decisions about the scheduling of future treatments.[36] Unlike previous studies, our study suggests that the relationship between pain and acceptance of peri-operative risk is negligible. However, most patients in our study were not in severe pain and reported satisfactory pain control with their current analgesic management. Further research is needed to explore the relationship between severe pain and acceptance of peri-operative risk

Of interest, the only significant correlation was between the predicted peri-operative risk (SAVS-CRI score) and the patient's perception of their peri-operative risk. This suggests that the patients understood the concept of surgery-associated risk. Consequently, the fact that patient decisions were strongly determined by perception of benefits, but weakly by perception of risks is suggestive, but does not point to a specific model of the patient decision process.

LIMITATIONS

Our study has several potential limitations:

- ✓ Most patients did not report severe pain and most participating patients did report satisfactory pain control with their current analgesic management.
- ✓ The majority of patients had impulsivity scores in the normal range.

It is possible that a study population with greater variation in both pain severity and impulsivity might enable the detection of an association.

- ✓ Our study population represents a predominantly relatively poorly educated patient population from a specific cultural group.

This may be an advantage as to date the majority of literature in the behavioural and cognitive sciences is based upon undergraduate students at highly developed western institutions

- ✓ We used an adapted VAS to assess the patients' perception of the benefits of surgery, perceived peri-operative risk and acceptance of peri-operative risk.

Whilst this may be criticised, we opted for an adapted VAS instead of other decision analysis instruments based on its simplicity and the low numeracy level of our study population.

- ✓ The subgroup of patients with carotid artery disease may have potentially confounded the relationship between pain and acceptance of peri-operative risk in this cohort.

A post hoc analysis was conducted where the patients with carotid artery disease were removed from the analysis and all study outcomes were unchanged. Again, the perceived benefit of surgery by the patient remained the only predictor of peri-operative risk acceptance (β 0.36, 95% CI 0.08–0.67, p = 0.013).

CONCLUSION

There are several factors that influence a patient's decision to proceed with surgery but the manner in which risks are balanced and information integrated still remains poorly understood. We have shown that the perceived benefit of surgery is an important predictor of acceptance of peri-operative risk. But, we have been unable to adequately address the importance of severe pain and an impulsive personality on acceptance of peri-operative risk. Further research is required to adequately address these issues.

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- Professor D Spurrett

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No. 7

Predictors of Peri-Operative Risk Acceptance by Vascular Surgery Patients at a Tertiary Level Hospital (MMED)

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School of Clinical Medicine

Discipline of Anaesthesiology and Critical Care

CONTENTS

PREDICTORS OF PERI-OPERATIVE RISK ACCEPTANCE BY VASCULAR SURGERY PATIENTS AT A TERTIARY LEVEL HOSPITAL (MMED)

INTRODUCTION

South African vascular surgical patients have an elevated cardiac risk following non-cardiac surgery and a high co-existent morbidity.[1, 2] The decision whether to proceed with surgery is multidimensional. Patients need to balance the considerations in favour of surgery with those favouring conservative treatment, which requires weighing peri-operative risk against morbidity associated with non-surgical treatment.

This study was conducted as part of my Masters in Medicine (MMED) in order to determine the potential predictors of peri-operative risk acceptance by South African vascular surgical patients at a tertiary level hospital in KwaZulu-Natal.

DEFINITIONS

Decision-making
A cognitive process in which available information is evaluated and integrated in order to reach a conclusion or a course of action among several alternative possibilities. [3]

Shared decision-making
This is a decision-making process involving collaboration between the patient and their physician to make medical decisions based on current evidence, and the patient's subjectivities. [4]

Peri-operative risk
This was defined as a risk of adverse outcomes associated with surgery during the hospital admission for surgery (e.g. death and major adverse cardiac events).

Visual analogue scale (VAS)
An instrument used to quantify subjective characteristics or attitudes that ranges across a continuum and cannot be measured directly. It is commonly represented as a horizontal line from 0mm to 100mm. The endpoints of the line represent the extremes of the parameter being measured.[5]

Impulsivity
A personality trait associated with willingness to take risks, lack of planning and future orientation, and making quick decisions.[6]

Barratt Impulsiveness Scale II (BIS II)
A self-reported instrument devised to assess the construct of impulsiveness.[7] It is composed of 30 items that are scored on a 4-point scale to yield a total score. The BIS II can be further divided into six first order factors (i.e. attention, motor, self-control, cognitive complexity, perseverance and cognitive instability impulsiveness) and three second order factors (i.e. attention, motor and non planning impulsiveness).[7] A total score of 72 represents a highly impulsive individual, a total

score of 52-71 represents the normal limits of impulsiveness and a total score of less than 52 represents a cautious individual.[7]

South African Vascular Surgical Cardiac Risk Index (SAVS-CRI)

A cardiovascular risk stratification index that can be used in South African patients undergoing vascular surgery to predict the risk of peri-operative major adverse cardiovascular events (MACEs).[8] It consists of the following six independent risk factors: patient's age, history of ischaemic heart disease, chronic β-blockade, a history of diabetes, a prior history of coronary revascularisation and the vascular surgical procedure.[8] A total score of <7 represents the low-risk group, a total score of 7-11 represents the intermediate-risk group and a total score of >11 represents the high-risk group.

BACKGROUND

There has been an increase in the number of patients undergoing non-cardiac surgery globally.[1,9] Vascular surgical patients have an elevated cardiac risk following non-cardiac surgery. Considerations in this group are varied from poor premorbid functioning, anatomical concerns, surgical complications, medical comorbidities and uncertainty of a suitable outcome. As a result, the decision-making process leading to surgical intervention is complex and creates a predicament for patients i.e. should they or should they not accept the peri-operative risk when consenting to vascular surgery in order to achieve a suitable outcome.[1, 2, 10, 11]

Decision-making is a cognitive function which reflects on the consequences of a certain choice[3] and requires deliberation on numerous alternatives and contemplation about future outcomes.[12] In the literature, 'decisions under ambiguity' and 'decisions under risk' are differentiated. Decisions under ambiguity represent situations where the results of the decision are not defined and there is no information regarding the probability of a positive or negative outcome whereas, decisions under risk are described as situations where the outcomes are stipulated and associated possibilities are identified or are quantifiable.[3, 13]

Recently, the concept of decision-making in medicine has progressed from solely the physician's recommendations on surgical intervention to the current concept of shared decision-making.[4]

Patient autonomy and their readiness to give informed consent for surgery are affected by a myriad of factors.[14] There are a multitude of studies, which have looked at decision-making processes in a variety of patient groups. For example, impaired decisions were shown in patients with orbitofrontal lesions,[3] drug addicts,[15-17] obesity,[18] obsessive compulsive disorder,[15] criminals,[19] fibromyalgia and temporomandibular disease.[20]

However, very few studies have related pain to a decision measure such as the study by Apkarian et al.[21, 22] They determined that chronic back pain and chronic regional pain syndrome patients performed worse on an emotional decision-making task that was assessed using the Iowa Gambling Task. [21] Furthermore, the poor performance of the chronic back pain patients was correlated to their pain intensity.[21] Another study suggested that the duration of pain and the intensity thereof were the most important factors for patients in their decision to proceed with lumbar spine fusion.[23, 24]

Based on clinical experience, it would appear that patients in severe pain are more inclined to accept risk than their counterparts in mild pain[24] but there still remains a paucity of published data to support this opinion and very few studies such as Bono et al[24] have shown that the severity of pain is the most important factor in a patient's decision to accept peri-operative risk when considering surgical intervention.

The aim of our study was to determine the proportional contributions of i) pain, ii) impulsivity, iii) patients' perception of the benefits of surgery, iv) patients' perception of peri-operative risk and v) predicted peri-operative risk on the acceptance of peri-operative risk by vascular surgical patients.

METHODS

Ethical approval for this study (Ethics Reference Number BE 391/13) was obtained from the Biomedical Research Ethics Committee and the Postgraduate Education Committee of the University of KwaZulu-Natal, South Africa on 20 February 2014.

Study setting
Inkosi Albert Luthuli Central Hospital, eThekwini District Complex, Durban, KwaZulu-Natal, South Africa.

Study design
Prospective, correlational study.

Population and Study Sample
Vascular surgical patients at Inkosi Albert Luthuli Central Hospital during April to June 2014.

Inclusion criteria:
All vascular surgical patients over 45 years of age who required surgery but in whom the decision to proceed with surgery had not yet been made.

Exclusion criteria:
Patients who declined to give informed consent to participate in the study.

Selection of Sample and Sample Size
We used random sampling from vascular surgical clinic patients. It had been determined that a minimum sample size of 55 would achieve 90% power to detect an R^2 of 0.20000 attributed to 3 independent variable(s) using an F-test with a significance level (α) of 0.01000. The variables tested were adjusted for an additional 3 independent variable(s) with an R^2 of 0.30000. Hence, we recruited 60 patients into our study.

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Predicted peri-operative risk - SAVS-CRI score	-0.26 (-5.48–0.08)	0.057

** β: standardised coefficient, † VAS: Visual analogue scale, ‡ BIS II: Barratt Impulsiveness Scale II, § SAVS-CRI: South African Vascular Surgical Cardiac Risk Index*

The perceived benefit of surgery by the patient (β 0.36, 95% CI 0.14–0.70, p = 0.005) was the only predictor of peri-operative risk acceptance. We did not find any statistically significant association between pain (β 0.07, 95% CI -0.16–0.28, p = 0.582), impulsivity (β 0.12, 95% CI -0.59–1.59, p = 0.360), the patients' perception of peri-operative risk (β -0.05, 95% CI -0.31–0.22, p = 0.711) and predicted peri-operative risk (β -0.26, 95% CI -5.48–0.08, p = 0.057) on acceptance of peri-operative risk in this population.

DISCUSSION

Our study demonstrated that the only significant predictor of acceptance of peri-operative risk is the perceived benefits of surgery by the patient. There were no statistically significant associations between pain, impulsivity, patients' perception of peri-operative risk and predicted peri-operative risk on the outcome of acceptance of peri-operative risk in this cohort.

There is a noticeable void in the literature as limited studies have investigated the factors, which influence acceptance of peri-operative risk by surgical patients.[23-27] Our findings are relevant, as this is the first study to determine the proportional contribution of pain, impulsivity, patients' perception of the benefits of surgery, patients' perception of peri-operative risk and predicted peri-operative risk on acceptance of peri-operative risk by a surgical population.

The only predictor of acceptance of peri-operative risk was the patients' perception of the benefits of surgery. According to the Institute of Medicine, 'patient-centered care' is one of the key components of health quality.[28] Shared decision-making plays a pivotal role in this paradigm.[28-31] The fundamentals of shared decision-making rely on the doctor collaborating with the patient to share information regarding the risks, benefits and limits of available treatment options that are based on current research evidence.[28-32] In doing so, a consensus on medical treatment is reached that is congruent with the patient's values, goals and preferences.[28-32] This ideal model of patient decision presupposes that patients receive accurate information about risks, costs and benefits, that they accurately represent that information when deliberating, and that their reasoning does not systematically drive them away from conclusions that are in their genuine interests. There is reason to doubt that these assumptions are generally true.[33]

Some personality traits such as impulsivity have been associated with decision-making deficits (i.e. an impulsive person exhibits reduced reflection on the consequences of their choice and has a high sensitivity to delayed rewards or a stronger preference for relatively immediate rewards).[15, 34, 35] Most patients in our study were not pathologically impulsive and there was no significant relationship between impulsivity and acceptance of peri-operative risk in our study. As a result we could not explore these associations further.

Another implication of our main finding is that patient involvement in treatment decision-making must be emphasised and the patient needs to actively participate in shared decision making. Further work should focus on understanding the impact of the surgical consultation on patient perception of surgery and in particular ascertaining what factors might be positively or negatively influencing patients' perception of surgery.

In general, limited research has been published which relates a decision measure to pain. Apkarian et al[21, 22] concluded that chronic back pain and chronic regional pain syndrome patients are significantly impaired on an emotional decision-making task (the Iowa Gambling Task) and the performance of chronic back pain patients was correlated to their pain intensity. In another study, Bono et al[24] determined that the severity of pain is the most important factor in patient's decision to accept surgical complications when considering lumbar spine fusion and Andrade et al found that recent pain influenced decisions about the scheduling of future treatments.[36] Unlike previous studies, our study suggests that the relationship between pain and acceptance of peri-operative risk is negligible. However, most patients in our study were not in severe pain and reported satisfactory pain control with their current analgesic management. Further research is needed to explore the relationship between severe pain and acceptance of peri-operative risk

Of interest, the only significant correlation was between the predicted peri-operative risk (SAVS-CRI score) and the patient's perception of their peri-operative risk. This suggests that the patients understood the concept of surgery-associated risk. Consequently, the fact that patient decisions were strongly determined by perception of benefits, but weakly by perception of risks is suggestive, but does not point to a specific model of the patient decision process.

LIMITATIONS

Our study has several potential limitations:

- ✓ Most patients did not report severe pain and most participating patients did report satisfactory pain control with their current analgesic management.
- ✓ The majority of patients had impulsivity scores in the normal range.

It is possible that a study population with greater variation in both pain severity and impulsivity might enable the detection of an association.

- ✓ Our study population represents a predominantly relatively poorly educated patient population from a specific cultural group.

This may be an advantage as to date the majority of literature in the behavioural and cognitive sciences is based upon undergraduate students at highly developed western institutions

- ✓ We used an adapted VAS to assess the patients' perception of the benefits of surgery, perceived peri-operative risk and acceptance of peri-operative risk.

Whilst this may be criticised, we opted for an adapted VAS instead of other decision analysis instruments based on its simplicity and the low numeracy level of our study population.

- ✓ The subgroup of patients with carotid artery disease may have potentially confounded the relationship between pain and acceptance of peri-operative risk in this cohort.

A post hoc analysis was conducted where the patients with carotid artery disease were removed from the analysis and all study outcomes were unchanged. Again, the perceived benefit of surgery by the patient remained the only predictor of peri-operative risk acceptance (β 0.36, 95% CI 0.08–0.67, p = 0.013).

CONCLUSION

There are several factors that influence a patient's decision to proceed with surgery but the manner in which risks are balanced and information integrated still remains poorly understood. We have shown that the perceived benefit of surgery is an important predictor of acceptance of peri-operative risk. But, we have been unable to adequately address the importance of severe pain and an impulsive personality on acceptance of peri-operative risk. Further research is required to adequately address these issues.

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- Professor BM Biccard
- Professor D Spurrett

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No. 7

Predictors of Peri-Operative Risk Acceptance by Vascular Surgery Patients at a Tertiary Level Hospital (MMED)

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CONTENTS

PREDICTORS OF PERI-OPERATIVE RISK ACCEPTANCE BY VASCULAR SURGERY PATIENTS AT A TERTIARY LEVEL HOSPITAL (MMED)

INTRODUCTION

South African vascular surgical patients have an elevated cardiac risk following non-cardiac surgery and a high co-existent morbidity.[1, 2] The decision whether to proceed with surgery is multidimensional. Patients need to balance the considerations in favour of surgery with those favouring conservative treatment, which requires weighing peri-operative risk against morbidity associated with non-surgical treatment.

This study was conducted as part of my Masters in Medicine (MMED) in order to determine the potential predictors of peri-operative risk acceptance by South African vascular surgical patients at a tertiary level hospital in KwaZulu-Natal.

DEFINITIONS

Decision-making
A cognitive process in which available information is evaluated and integrated in order to reach a conclusion or a course of action among several alternative possibilities. [3]

Shared decision-making
This is a decision-making process involving collaboration between the patient and their physician to make medical decisions based on current evidence, and the patient's subjectivities. [4]

Peri-operative risk
This was defined as a risk of adverse outcomes associated with surgery during the hospital admission for surgery (e.g. death and major adverse cardiac events).

Visual analogue scale (VAS)
An instrument used to quantify subjective characteristics or attitudes that ranges across a continuum and cannot be measured directly. It is commonly represented as a horizontal line from 0mm to 100mm. The endpoints of the line represent the extremes of the parameter being measured.[5]

Impulsivity
A personality trait associated with willingness to take risks, lack of planning and future orientation, and making quick decisions.[6]

Barratt Impulsiveness Scale II (BIS II)
A self-reported instrument devised to assess the construct of impulsiveness.[7] It is composed of 30 items that are scored on a 4-point scale to yield a total score. The BIS II can be further divided into six first order factors (i.e. attention, motor, self-control, cognitive complexity, perseverance and cognitive instability impulsiveness) and three second order factors (i.e. attention, motor and non planning impulsiveness).[7] A total score of 72 represents a highly impulsive individual, a total

score of 52-71 represents the normal limits of impulsiveness and a total score of less than 52 represents a cautious individual.[7]

South African Vascular Surgical Cardiac Risk Index (SAVS-CRI)

A cardiovascular risk stratification index that can be used in South African patients undergoing vascular surgery to predict the risk of peri-operative major adverse cardiovascular events (MACEs).[8] It consists of the following six independent risk factors: patient's age, history of ischaemic heart disease, chronic β-blockade, a history of diabetes, a prior history of coronary revascularisation and the vascular surgical procedure.[8] A total score of <7 represents the low-risk group, a total score of 7-11 represents the intermediate-risk group and a total score of >11 represents the high-risk group.

BACKGROUND

There has been an increase in the number of patients undergoing non-cardiac surgery globally.[1,9] Vascular surgical patients have an elevated cardiac risk following non-cardiac surgery. Considerations in this group are varied from poor premorbid functioning, anatomical concerns, surgical complications, medical comorbidities and uncertainty of a suitable outcome. As a result, the decision-making process leading to surgical intervention is complex and creates a predicament for patients i.e. should they or should they not accept the peri-operative risk when consenting to vascular surgery in order to achieve a suitable outcome.[1, 2, 10, 11]

Decision-making is a cognitive function which reflects on the consequences of a certain choice[3] and requires deliberation on numerous alternatives and contemplation about future outcomes.[12] In the literature, 'decisions under ambiguity' and 'decisions under risk' are differentiated. Decisions under ambiguity represent situations where the results of the decision are not defined and there is no information regarding the probability of a positive or negative outcome whereas, decisions under risk are described as situations where the outcomes are stipulated and associated possibilities are identified or are quantifiable.[3, 13]

Recently, the concept of decision-making in medicine has progressed from solely the physician's recommendations on surgical intervention to the current concept of shared decision-making.[4]

Patient autonomy and their readiness to give informed consent for surgery are affected by a myriad of factors.[14] There are a multitude of studies, which have looked at decision-making processes in a variety of patient groups. For example, impaired decisions were shown in patients with orbitofrontal lesions,[3] drug addicts,[15-17] obesity,[18] obsessive compulsive disorder,[15] criminals,[19] fibromyalgia and temporomandibular disease.[20]

However, very few studies have related pain to a decision measure such as the study by Apkarian et al.[21, 22] They determined that chronic back pain and chronic regional pain syndrome patients performed worse on an emotional decision-making task that was assessed using the Iowa Gambling Task. [21] Furthermore, the poor performance of the chronic back pain patients was correlated to their pain intensity.[21] Another study suggested that the duration of pain and the intensity thereof were the most important factors for patients in their decision to proceed with lumbar spine fusion.[23, 24]

Based on clinical experience, it would appear that patients in severe pain are more inclined to accept risk than their counterparts in mild pain[24] but there still remains a paucity of published data to support this opinion and very few studies such as Bono et al[24] have shown that the severity of pain is the most important factor in a patient's decision to accept peri-operative risk when considering surgical intervention.

The aim of our study was to determine the proportional contributions of i) pain, ii) impulsivity, iii) patients' perception of the benefits of surgery, iv) patients' perception of peri-operative risk and v) predicted peri-operative risk on the acceptance of peri-operative risk by vascular surgical patients.

METHODS

Ethical approval for this study (Ethics Reference Number BE 391/13) was obtained from the Biomedical Research Ethics Committee and the Postgraduate Education Committee of the University of KwaZulu-Natal, South Africa on 20 February 2014.

Study setting
Inkosi Albert Luthuli Central Hospital, eThekwini District Complex, Durban, KwaZulu-Natal, South Africa.

Study design
Prospective, correlational study.

Population and Study Sample
Vascular surgical patients at Inkosi Albert Luthuli Central Hospital during April to June 2014.

Inclusion criteria:
All vascular surgical patients over 45 years of age who required surgery but in whom the decision to proceed with surgery had not yet been made.

Exclusion criteria:
Patients who declined to give informed consent to participate in the study.

Selection of Sample and Sample Size
We used random sampling from vascular surgical clinic patients. It had been determined that a minimum sample size of 55 would achieve 90% power to detect an R^2 of 0.20000 attributed to 3 independent variable(s) using an F-test with a significance level (α) of 0.01000. The variables tested were adjusted for an additional 3 independent variable(s) with an R^2 of 0.30000. Hence, we recruited 60 patients into our study.

Sources of Data
A structured standardised questionnaire was designed and administered to the vascular surgical patients in either English or isiZulu. A pilot study was conducted at the same site in March 2014. These patients were not included in the final study but their responses and queries were used to improve the structured standardised questionnaire.

Our questionnaire consisted of the following sections:

1. Demographic data (age, sex, race, highest level of education)
2. Pain Assessment which contained a pain VAS and an assessment of the efficacy of current analgesic management
3. Impulsivity screen using the Barratt Impulsiveness Scale II (BIS II)
4. Patients' perception of surgery i.e. the perceived benefits of surgery and perceived peri-operative risk by using an adapted VAS
5. Patients' predicted peri-operative risk according to the South African Vascular Surgical Cardiac Risk Index (SAVS-CRI)
6. Acceptance of predicted peri-operative risk using an adapted VAS

Measures to Ensure Validity

1. Internal
   A pilot study was conducted at the same site in March 2014 and served to validate the questionnaire and clarify any misconceptions.
2. Reduction of bias
   Selection bias - Random sampling was conducted from vascular surgical clinic patients in whom the decision to proceed with surgery had not yet been made
   Information bias - Questionnaires were anonymous.
3. External
   This study was conducted at one site only (Inkosi Albert Luthuli Central Hospital).

Collection of Data

A one on one structured standardised questionnaire was administered to the patients by the principal investigator.

Exposure Assessment

Acceptance of peri-operative risk using an adapted VAS.

Data Management

Data was collected on paper case record forms for every patient recruited. Data was input into Microsoft excel and kept anonymous. Access was username and password protected by the investigators.

Data Analysis Strategies

Categorical data were analysed using descriptive statistics and presented as proportions. Continuous data were analysed using descriptive statistics and presented as mean and standard deviation. The association between the potential determinants of the acceptance of surgical risk were analysed using Pearson's correlation coefficient, as all variables were normally distributed. Linear regression analysis was used to determine independent predictors of an acceptance of peri-operative risk. A p-value of < 0.05 was considered to be statistically significant. Results are presented as odds ratios (OR) and 95% confidence intervals (CI). All statistical analyses were performed using SPSS version 22.

RESULTS

Sixty patients were prospectively recruited into the study between April 2014 and June 2014. The characteristics of our study cohort are shown in Table 1.

Table 1 Baseline patient characteristics, expressed as mean (standard deviation) or number (proportion).

	Total (n = 60)
Age; years	64.15 (9.7)
Sex	
Male	37 (61.7%)
Female	23 (38.3%)
Highest level of education	
Tertiary	6 (10%)
High school or less	54 (90%)
Pain VAS score; mm	57.05 (33.02)
BIS II score	63.83 (6.97)
Surgical diagnosis	
Peripheral vascular disease	48 (80%)
Carotid artery disease	7 (11.7%)
Carotid artery disease and peripheral vascular disease	4 (6.7%)
Infra renal abdominal aortic aneurysm	1 (1.7%)
Patients' perception of the benefits of surgery VAS score; mm	74.95 (25.09)
Patients' perception of peri-operative risk VAS score; mm	40.13 (29.55)
SAVS-CRI score	6.7 (2.8)
SAVS-CRI risk group	
High	1 (1.7%)
Intermediate	32 (53.3%)
Low	27 (45%)
Actual subsequent patient management	
Conservative management	13 (21.7%)
Surgery	47 (78.3%)

** VAS: Visual analogue scale, † mm: millimetres, ‡ BIS II: Barratt Impulsiveness Scale II, § SAVS-CRI: South African Vascular Surgical Cardiac Risk Index*

The majority of the patients had a high school or lower level of education. Approximately 10% of the cohort had no pain (VAS 0mm) and their primary diagnosis was predominantly carotid artery disease. The remainder of the cohort reported moderate to severe pain (mean VAS 57.05mm, SD 33.02) and the primary diagnosis in 80% of our cohort was peripheral vascular disease. In addition, 6.7% of patients had maximal pain (VAS 100mm) and their primary diagnosis was peripheral vascular disease. Fifty patients (83%) had a Barratt Impulsiveness Scale II (BIS II) score of 52-71, which is by definition normal (mean BIS II score 63.83, SD 6.97).

The only significant correlation was between the predicted peri-operative risk (SAVS-CRI score) and the patients' perception of their peri-operative risk (r = 0.33 p = 0.01). The remaining correlations between the potential predictors of acceptance of peri-operative risk were not statistically significant.

The results of the linear regression are shown in Table 2.

Table 2 Linear regression analysis for acceptance of peri-operative risk by vascular surgical patients.

	β (95% CI)	p value
Pain VAS score	0.07 (-0.16–0.28)	0.582
BIS II score	0.12 (-0.59–1.59)	0.360
Patients' perception of the benefits of surgery VAS score	0.36 (0.14–0.70)	0.005
Patients' perception of peri-operative risk VAS score	-0.05 (-0.31–0.22)	0.711
Predicted peri-operative risk - SAVS-CRI score	-0.26 (-5.48–0.08)	0.057

** β: standardised coefficient, † VAS: Visual analogue scale, ‡ BIS II: Barratt Impulsiveness Scale II, § SAVS-CRI: South African Vascular Surgical Cardiac Risk Index*

The perceived benefit of surgery by the patient (β 0.36, 95% CI 0.14–0.70, p = 0.005) was the only predictor of peri-operative risk acceptance. We did not find any statistically significant association between pain (β 0.07, 95% CI -0.16–0.28, p = 0.582), impulsivity (β 0.12, 95% CI -0.59–1.59, p = 0.360), the patients' perception of peri-operative risk (β -0.05, 95% CI -0.31–0.22, p = 0.711) and predicted peri-operative risk (β -0.26, 95% CI -5.48–0.08, p = 0.057) on acceptance of peri-operative risk in this population.

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Our study demonstrated that the only significant predictor of acceptance of peri-operative risk is the perceived benefits of surgery by the patient. There were no statistically significant associations between pain, impulsivity, patients' perception of peri-operative risk and predicted peri-operative risk on the outcome of acceptance of peri-operative risk in this cohort.

There is a noticeable void in the literature as limited studies have investigated the factors, which influence acceptance of peri-operative risk by surgical patients.[23-27] Our findings are relevant, as this is the first study to determine the proportional contribution of pain, impulsivity, patients' perception of the benefits of surgery, patients' perception of peri-operative risk and predicted peri-operative risk on acceptance of peri-operative risk by a surgical population.

The only predictor of acceptance of peri-operative risk was the patients' perception of the benefits of surgery. According to the Institute of Medicine, 'patient-centered care' is one of the key components of health quality.[28] Shared decision-making plays a pivotal role in this paradigm.[28-31] The fundamentals of shared decision-making rely on the doctor collaborating with the patient to share information regarding the risks, benefits and limits of available treatment options that are based on current research evidence.[28-32] In doing so, a consensus on medical treatment is reached that is congruent with the patient's values, goals and preferences.[28-32] This ideal model of patient decision presupposes that patients receive accurate information about risks, costs and benefits, that they accurately represent that information when deliberating, and that their reasoning does not systematically drive them away from conclusions that are in their genuine interests. There is reason to doubt that these assumptions are generally true.[33]

Some personality traits such as impulsivity have been associated with decision-making deficits (i.e. an impulsive person exhibits reduced reflection on the consequences of their choice and has a high sensitivity to delayed rewards or a stronger preference for relatively immediate rewards).[15, 34, 35] Most patients in our study were not pathologically impulsive and there was no significant relationship between impulsivity and acceptance of peri-operative risk in our study. As a result we could not explore these associations further.

Another implication of our main finding is that patient involvement in treatment decision-making must be emphasised and the patient needs to actively participate in shared decision making. Further work should focus on understanding the impact of the surgical consultation on patient perception of surgery and in particular ascertaining what factors might be positively or negatively influencing patients' perception of surgery.

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Of interest, the only significant correlation was between the predicted peri-operative risk (SAVS-CRI score) and the patient's perception of their peri-operative risk. This suggests that the patients understood the concept of surgery-associated risk. Consequently, the fact that patient decisions were strongly determined by perception of benefits, but weakly by perception of risks is suggestive, but does not point to a specific model of the patient decision process.

LIMITATIONS

Our study has several potential limitations:

- ✓ Most patients did not report severe pain and most participating patients did report satisfactory pain control with their current analgesic management.
- ✓ The majority of patients had impulsivity scores in the normal range.

It is possible that a study population with greater variation in both pain severity and impulsivity might enable the detection of an association.

- ✓ Our study population represents a predominantly relatively poorly educated patient population from a specific cultural group.

This may be an advantage as to date the majority of literature in the behavioural and cognitive sciences is based upon undergraduate students at highly developed western institutions

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Whilst this may be criticised, we opted for an adapted VAS instead of other decision analysis instruments based on its simplicity and the low numeracy level of our study population.

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A post hoc analysis was conducted where the patients with carotid artery disease were removed from the analysis and all study outcomes were unchanged. Again, the perceived benefit of surgery by the patient remained the only predictor of peri-operative risk acceptance (β 0.36, 95% CI 0.08–0.67, p = 0.013).

CONCLUSION

There are several factors that influence a patient's decision to proceed with surgery but the manner in which risks are balanced and information integrated still remains poorly understood. We have shown that the perceived benefit of surgery is an important predictor of acceptance of peri-operative risk. But, we have been unable to adequately address the importance of severe pain and an impulsive personality on acceptance of peri-operative risk. Further research is required to adequately address these issues.

ACKNOWLEDGEMENTS

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No. 7

Predictors of Peri-Operative Risk Acceptance by Vascular Surgery Patients at a Tertiary Level Hospital (MMED)

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CONTENTS

PREDICTORS OF PERI-OPERATIVE RISK ACCEPTANCE BY VASCULAR SURGERY PATIENTS AT A TERTIARY LEVEL HOSPITAL (MMED)

INTRODUCTION

South African vascular surgical patients have an elevated cardiac risk following non-cardiac surgery and a high co-existent morbidity.[1, 2] The decision whether to proceed with surgery is multidimensional. Patients need to balance the considerations in favour of surgery with those favouring conservative treatment, which requires weighing peri-operative risk against morbidity associated with non-surgical treatment.

This study was conducted as part of my Masters in Medicine (MMED) in order to determine the potential predictors of peri-operative risk acceptance by South African vascular surgical patients at a tertiary level hospital in KwaZulu-Natal.

DEFINITIONS

Decision-making
A cognitive process in which available information is evaluated and integrated in order to reach a conclusion or a course of action among several alternative possibilities. [3]

Shared decision-making
This is a decision-making process involving collaboration between the patient and their physician to make medical decisions based on current evidence, and the patient's subjectivities. [4]

Peri-operative risk
This was defined as a risk of adverse outcomes associated with surgery during the hospital admission for surgery (e.g. death and major adverse cardiac events).

Visual analogue scale (VAS)
An instrument used to quantify subjective characteristics or attitudes that ranges across a continuum and cannot be measured directly. It is commonly represented as a horizontal line from 0mm to 100mm. The endpoints of the line represent the extremes of the parameter being measured.[5]

Impulsivity
A personality trait associated with willingness to take risks, lack of planning and future orientation, and making quick decisions.[6]

Barratt Impulsiveness Scale II (BIS II)
A self-reported instrument devised to assess the construct of impulsiveness.[7] It is composed of 30 items that are scored on a 4-point scale to yield a total score. The BIS II can be further divided into six first order factors (i.e. attention, motor, self-control, cognitive complexity, perseverance and cognitive instability impulsiveness) and three second order factors (i.e. attention, motor and non planning impulsiveness).[7] A total score of 72 represents a highly impulsive individual, a total

score of 52-71 represents the normal limits of impulsiveness and a total score of less than 52 represents a cautious individual.[7]

South African Vascular Surgical Cardiac Risk Index (SAVS-CRI)

A cardiovascular risk stratification index that can be used in South African patients undergoing vascular surgery to predict the risk of peri-operative major adverse cardiovascular events (MACEs).[8] It consists of the following six independent risk factors: patient's age, history of ischaemic heart disease, chronic β-blockade, a history of diabetes, a prior history of coronary revascularisation and the vascular surgical procedure.[8] A total score of <7 represents the low-risk group, a total score of 7-11 represents the intermediate-risk group and a total score of >11 represents the high-risk group.

BACKGROUND

There has been an increase in the number of patients undergoing non-cardiac surgery globally.[1,9] Vascular surgical patients have an elevated cardiac risk following non-cardiac surgery. Considerations in this group are varied from poor premorbid functioning, anatomical concerns, surgical complications, medical comorbidities and uncertainty of a suitable outcome. As a result, the decision-making process leading to surgical intervention is complex and creates a predicament for patients i.e. should they or should they not accept the peri-operative risk when consenting to vascular surgery in order to achieve a suitable outcome.[1, 2, 10, 11]

Decision-making is a cognitive function which reflects on the consequences of a certain choice[3] and requires deliberation on numerous alternatives and contemplation about future outcomes.[12] In the literature, 'decisions under ambiguity' and 'decisions under risk' are differentiated. Decisions under ambiguity represent situations where the results of the decision are not defined and there is no information regarding the probability of a positive or negative outcome whereas, decisions under risk are described as situations where the outcomes are stipulated and associated possibilities are identified or are quantifiable.[3, 13]

Recently, the concept of decision-making in medicine has progressed from solely the physician's recommendations on surgical intervention to the current concept of shared decision-making.[4]

Patient autonomy and their readiness to give informed consent for surgery are affected by a myriad of factors.[14] There are a multitude of studies, which have looked at decision-making processes in a variety of patient groups. For example, impaired decisions were shown in patients with orbitofrontal lesions,[3] drug addicts,[15-17] obesity,[18] obsessive compulsive disorder,[15] criminals,[19] fibromyalgia and temporomandibular disease.[20]

However, very few studies have related pain to a decision measure such as the study by Apkarian et al.[21, 22] They determined that chronic back pain and chronic regional pain syndrome patients performed worse on an emotional decision-making task that was assessed using the Iowa Gambling Task. [21] Furthermore, the poor performance of the chronic back pain patients was correlated to their pain intensity.[21] Another study suggested that the duration of pain and the intensity thereof were the most important factors for patients in their decision to proceed with lumbar spine fusion.[23, 24]

Based on clinical experience, it would appear that patients in severe pain are more inclined to accept risk than their counterparts in mild pain[24] but there still remains a paucity of published data to support this opinion and very few studies such as Bono et al[24] have shown that the severity of pain is the most important factor in a patient's decision to accept peri-operative risk when considering surgical intervention.

The aim of our study was to determine the proportional contributions of i) pain, ii) impulsivity, iii) patients' perception of the benefits of surgery, iv) patients' perception of peri-operative risk and v) predicted peri-operative risk on the acceptance of peri-operative risk by vascular surgical patients.

METHODS

Ethical approval for this study (Ethics Reference Number BE 391/13) was obtained from the Biomedical Research Ethics Committee and the Postgraduate Education Committee of the University of KwaZulu-Natal, South Africa on 20 February 2014.

Study setting
Inkosi Albert Luthuli Central Hospital, eThekwini District Complex, Durban, KwaZulu-Natal, South Africa.

Study design
Prospective, correlational study.

Population and Study Sample
Vascular surgical patients at Inkosi Albert Luthuli Central Hospital during April to June 2014.

Inclusion criteria:
All vascular surgical patients over 45 years of age who required surgery but in whom the decision to proceed with surgery had not yet been made.

Exclusion criteria:
Patients who declined to give informed consent to participate in the study.

Selection of Sample and Sample Size
We used random sampling from vascular surgical clinic patients. It had been determined that a minimum sample size of 55 would achieve 90% power to detect an R^2 of 0.20000 attributed to 3 independent variable(s) using an F-test with a significance level (α) of 0.01000. The variables tested were adjusted for an additional 3 independent variable(s) with an R^2 of 0.30000. Hence, we recruited 60 patients into our study.

Sources of Data
A structured standardised questionnaire was designed and administered to the vascular surgical patients in either English or isiZulu. A pilot study was conducted at the same site in March 2014. These patients were not included in the final study but their responses and queries were used to improve the structured standardised questionnaire.

Our questionnaire consisted of the following sections:

1. Demographic data (age, sex, race, highest level of education)
2. Pain Assessment which contained a pain VAS and an assessment of the efficacy of current analgesic management
3. Impulsivity screen using the Barratt Impulsiveness Scale II (BIS II)
4. Patients' perception of surgery i.e. the perceived benefits of surgery and perceived peri-operative risk by using an adapted VAS
5. Patients' predicted peri-operative risk according to the South African Vascular Surgical Cardiac Risk Index (SAVS-CRI)
6. Acceptance of predicted peri-operative risk using an adapted VAS

Measures to Ensure Validity

1. Internal
   A pilot study was conducted at the same site in March 2014 and served to validate the questionnaire and clarify any misconceptions.
2. Reduction of bias
   Selection bias - Random sampling was conducted from vascular surgical clinic patients in whom the decision to proceed with surgery had not yet been made
   Information bias - Questionnaires were anonymous.
3. External
   This study was conducted at one site only (Inkosi Albert Luthuli Central Hospital).

Collection of Data

A one on one structured standardised questionnaire was administered to the patients by the principal investigator.

Exposure Assessment

Acceptance of peri-operative risk using an adapted VAS.

Data Management

Data was collected on paper case record forms for every patient recruited. Data was input into Microsoft excel and kept anonymous. Access was username and password protected by the investigators.

Data Analysis Strategies

Categorical data were analysed using descriptive statistics and presented as proportions. Continuous data were analysed using descriptive statistics and presented as mean and standard deviation. The association between the potential determinants of the acceptance of surgical risk were analysed using Pearson's correlation coefficient, as all variables were normally distributed. Linear regression analysis was used to determine independent predictors of an acceptance of peri-operative risk. A p-value of < 0.05 was considered to be statistically significant. Results are presented as odds ratios (OR) and 95% confidence intervals (CI). All statistical analyses were performed using SPSS version 22.

RESULTS

Sixty patients were prospectively recruited into the study between April 2014 and June 2014. The characteristics of our study cohort are shown in Table 1.

Table 1 Baseline patient characteristics, expressed as mean (standard deviation) or number (proportion).

	Total (n = 60)
Age; years	64.15 (9.7)
Sex	
Male	37 (61.7%)
Female	23 (38.3%)
Highest level of education	
Tertiary	6 (10%)
High school or less	54 (90%)
Pain VAS score; mm	57.05 (33.02)
BIS II score	63.83 (6.97)
Surgical diagnosis	
Peripheral vascular disease	48 (80%)
Carotid artery disease	7 (11.7%)
Carotid artery disease and peripheral vascular disease	4 (6.7%)
Infra renal abdominal aortic aneurysm	1 (1.7%)
Patients' perception of the benefits of surgery VAS score; mm	74.95 (25.09)
Patients' perception of peri-operative risk VAS score; mm	40.13 (29.55)
SAVS-CRI score	6.7 (2.8)
SAVS-CRI risk group	
High	1 (1.7%)
Intermediate	32 (53.3%)
Low	27 (45%)
Actual subsequent patient management	
Conservative management	13 (21.7%)
Surgery	47 (78.3%)

** VAS: Visual analogue scale, † mm: millimetres, ‡ BIS II: Barratt Impulsiveness Scale II, § SAVS-CRI: South African Vascular Surgical Cardiac Risk Index*

The majority of the patients had a high school or lower level of education. Approximately 10% of the cohort had no pain (VAS 0mm) and their primary diagnosis was predominantly carotid artery disease. The remainder of the cohort reported moderate to severe pain (mean VAS 57.05mm, SD 33.02) and the primary diagnosis in 80% of our cohort was peripheral vascular disease. In addition, 6.7% of patients had maximal pain (VAS 100mm) and their primary diagnosis was peripheral vascular disease. Fifty patients (83%) had a Barratt Impulsiveness Scale II (BIS II) score of 52-71, which is by definition normal (mean BIS II score 63.83, SD 6.97).

The only significant correlation was between the predicted peri-operative risk (SAVS-CRI score) and the patients' perception of their peri-operative risk (r = 0.33 p = 0.01). The remaining correlations between the potential predictors of acceptance of peri-operative risk were not statistically significant.

The results of the linear regression are shown in Table 2.

Table 2 Linear regression analysis for acceptance of peri-operative risk by vascular surgical patients.

	β (95% CI)	p value
Pain VAS score	0.07 (-0.16–0.28)	0.582
BIS II score	0.12 (-0.59–1.59)	0.360
Patients' perception of the benefits of surgery VAS score	0.36 (0.14–0.70)	0.005
Patients' perception of peri-operative risk VAS score	-0.05 (-0.31–0.22)	0.711
Predicted peri-operative risk - SAVS-CRI score	-0.26 (-5.48–0.08)	0.057

** β: standardised coefficient, † VAS: Visual analogue scale, ‡ BIS II: Barratt Impulsiveness Scale II, § SAVS-CRI: South African Vascular Surgical Cardiac Risk Index*

The perceived benefit of surgery by the patient (β 0.36, 95% CI 0.14–0.70, p = 0.005) was the only predictor of peri-operative risk acceptance. We did not find any statistically significant association between pain (β 0.07, 95% CI -0.16–0.28, p = 0.582), impulsivity (β 0.12, 95% CI -0.59–1.59, p = 0.360), the patients' perception of peri-operative risk (β -0.05, 95% CI -0.31–0.22, p = 0.711) and predicted peri-operative risk (β -0.26, 95% CI -5.48–0.08, p = 0.057) on acceptance of peri-operative risk in this population.

DISCUSSION

Our study demonstrated that the only significant predictor of acceptance of peri-operative risk is the perceived benefits of surgery by the patient. There were no statistically significant associations between pain, impulsivity, patients' perception of peri-operative risk and predicted peri-operative risk on the outcome of acceptance of peri-operative risk in this cohort.

There is a noticeable void in the literature as limited studies have investigated the factors, which influence acceptance of peri-operative risk by surgical patients.[23-27] Our findings are relevant, as this is the first study to determine the proportional contribution of pain, impulsivity, patients' perception of the benefits of surgery, patients' perception of peri-operative risk and predicted peri-operative risk on acceptance of peri-operative risk by a surgical population.

The only predictor of acceptance of peri-operative risk was the patients' perception of the benefits of surgery. According to the Institute of Medicine, 'patient-centered care' is one of the key components of health quality.[28] Shared decision-making plays a pivotal role in this paradigm.[28-31] The fundamentals of shared decision-making rely on the doctor collaborating with the patient to share information regarding the risks, benefits and limits of available treatment options that are based on current research evidence.[28-32] In doing so, a consensus on medical treatment is reached that is congruent with the patient's values, goals and preferences.[28-32] This ideal model of patient decision presupposes that patients receive accurate information about risks, costs and benefits, that they accurately represent that information when deliberating, and that their reasoning does not systematically drive them away from conclusions that are in their genuine interests. There is reason to doubt that these assumptions are generally true.[33]

Some personality traits such as impulsivity have been associated with decision-making deficits (i.e. an impulsive person exhibits reduced reflection on the consequences of their choice and has a high sensitivity to delayed rewards or a stronger preference for relatively immediate rewards).[15, 34, 35] Most patients in our study were not pathologically impulsive and there was no significant relationship between impulsivity and acceptance of peri-operative risk in our study. As a result we could not explore these associations further.

Another implication of our main finding is that patient involvement in treatment decision-making must be emphasised and the patient needs to actively participate in shared decision making. Further work should focus on understanding the impact of the surgical consultation on patient perception of surgery and in particular ascertaining what factors might be positively or negatively influencing patients' perception of surgery.

In general, limited research has been published which relates a decision measure to pain. Apkarian et al[21, 22] concluded that chronic back pain and chronic regional pain syndrome patients are significantly impaired on an emotional decision-making task (the Iowa Gambling Task) and the performance of chronic back pain patients was correlated to their pain intensity. In another study, Bono et al[24] determined that the severity of pain is the most important factor in patient's decision to accept surgical complications when considering lumbar spine fusion and Andrade et al found that recent pain influenced decisions about the scheduling of future treatments.[36] Unlike previous studies, our study suggests that the relationship between pain and acceptance of peri-operative risk is negligible. However, most patients in our study were not in severe pain and reported satisfactory pain control with their current analgesic management. Further research is needed to explore the relationship between severe pain and acceptance of peri-operative risk

Of interest, the only significant correlation was between the predicted peri-operative risk (SAVS-CRI score) and the patient's perception of their peri-operative risk. This suggests that the patients understood the concept of surgery-associated risk. Consequently, the fact that patient decisions were strongly determined by perception of benefits, but weakly by perception of risks is suggestive, but does not point to a specific model of the patient decision process.

LIMITATIONS

Our study has several potential limitations:

- ✓ Most patients did not report severe pain and most participating patients did report satisfactory pain control with their current analgesic management.
- ✓ The majority of patients had impulsivity scores in the normal range.

It is possible that a study population with greater variation in both pain severity and impulsivity might enable the detection of an association.

- ✓ Our study population represents a predominantly relatively poorly educated patient population from a specific cultural group.

This may be an advantage as to date the majority of literature in the behavioural and cognitive sciences is based upon undergraduate students at highly developed western institutions

- ✓ We used an adapted VAS to assess the patients' perception of the benefits of surgery, perceived peri-operative risk and acceptance of peri-operative risk.

Whilst this may be criticised, we opted for an adapted VAS instead of other decision analysis instruments based on its simplicity and the low numeracy level of our study population.

- ✓ The subgroup of patients with carotid artery disease may have potentially confounded the relationship between pain and acceptance of peri-operative risk in this cohort.

A post hoc analysis was conducted where the patients with carotid artery disease were removed from the analysis and all study outcomes were unchanged. Again, the perceived benefit of surgery by the patient remained the only predictor of peri-operative risk acceptance (β 0.36, 95% CI 0.08–0.67, p = 0.013).

CONCLUSION

There are several factors that influence a patient's decision to proceed with surgery but the manner in which risks are balanced and information integrated still remains poorly understood. We have shown that the perceived benefit of surgery is an important predictor of acceptance of peri-operative risk. But, we have been unable to adequately address the importance of severe pain and an impulsive personality on acceptance of peri-operative risk. Further research is required to adequately address these issues.

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